



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/560,204

12/08/2005

Masaaki Teramoto

10921.373USWO

5649

52835

7590

04/17/2009

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,204	TERAMOTO, MASAOKI	
	Examiner	Art Unit	
	Sally A. Sakelaris	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2009, 12/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 – 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 2 is generally narrative and indefinite, failing to conform with current U.S. practice. The claims appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Specifically, claim 2 recites an area "in a perpendicular direction which is perpendicular to a movement direction". A perpendicular direction that is perpendicular to another direction may be parallel and therefore this claim is confusing. Appropriate clarification is suggested.

Claim Rejections - 35 USC § 102

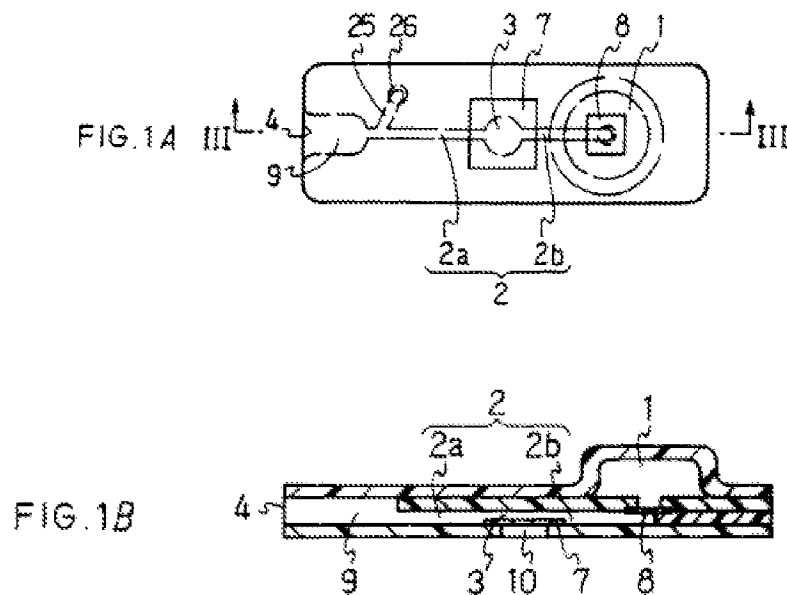
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 5-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Naka et al. (US 6325975).

With regard to claim 1, Naka et al teach a suction device for sample analysis that comprises the below device:



The device comprises a flow path 2, a sample introduction port 4, a liquid reservoir for reserving the sample to be introduced into the flow path 9.

With regard to claims 2 and 3, the width of the liquid reservoir or pooling portion, 9 is about 4 times that of the drawing channel 2 (Col. 6 lines 9-12 and Fig 1A).

With regard to claim 5, figure 1b above depicts the provision of the reservoir and flow path on a plate member and the thickness dimension of 9 being larger than the thickness dimension of 2a.

With regard to claim 6, a width dimension of 9 near the intersection with 2a are equal or generally equal to each other.

With regard to claims 7 and 8, Naka teaches the 2 spacers (7 and 8) defining the thickness directions of both 9 and 2 with one located between between the first and second plate members.

With regard to claims 9-12, Fig. 2 below shows the at least one spacer 8 is placed between the film 13 and the film 12 in a position to be a certain place in the drawing channel 2b. In layers 12 and 13, cut-out portions for forming the liquid pooling portion, 9 are made. In this state, the four layers 14, 13, 12, and 11 are laminated in this order so that the sample analysis device can be made. The cutout has a width that increases as the cutout extends away from the flow path.

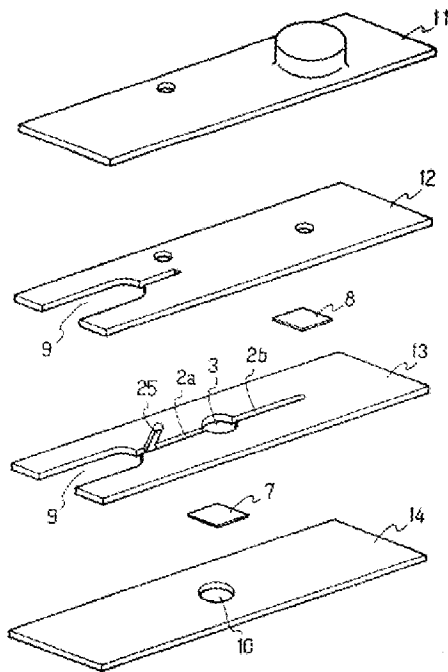


FIG. 2

With regard to claim 13, in the film 11, an approximately cylindrical convex portion or bulge, is formed to secure the capacity of the liquid reservoir through suction.

With regard to claims 14-16, the sample introduction port is open in the thickness direction, 4. The first plate and the second plate include a recess denting by way of 7 and the formed window 10 under the analysis section 3.

With regard to claim 17, the sample device uses capillarity to move the fluids within it (Col. 1 lines 28-31).

With regard to claims 18 and 19, an analysis section is formed as 3 in a certain position in the drawing channel 2 to receive a biochemical sample. The window of the analysis section 10 may be formed when glucose oxidase (GOD) is used as a reagent, because the reagent requires oxygen for color development(Col. 5, lines 42-51).

With regard to claim 20, the first half of this claim is a recitation of intended use and as it does not appear the use results in a structural feature the only limitation to be taught by the prior art is that of the sample introduction port's shape. Naka et al teach a generally circular sample introduction port in their 4 formed at the end of 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1797

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al.(6325975) in view of Quake et al.(US 2002/0037499 A1).

Naka et al's teaching can be seen above. With regard to this claim, Naka teaches the dimensions of the liquid reservoir to be 2 to 10mm in length, 2 to 10mm in width, and 0.2 to 1mm in thickness. With regard to the drawing channel Naka teaches 10 to 40mm by .5 to 2mm by .1 to .5mm.

Naka et al do not teach the capacity of the liquid reservoir to be set to 2 to 4 ul and the capacity of the flow path to be no more than 2 ul.

Quake et al teach a microfluidic device for analyte measurement with integrated active flux wherein using such microfluidic devices, the amount of sample volume needed for analysis is greatly reduced. For example, in preferred embodiments sample volumes between about 1-500ul and more preferably between about 1-100ul can be loaded into a sample well of the microfluidic device. In other embodiments, sample volumes of less than 1ul can be used [0400].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have scaled the apparatus of Naka et al. to the size of Quake's lab-on-a-chip device that uses a sample size that is several orders of magnitude less than is needed for conventional methods so only a few droplets of a blood sample are required instead of many cubic centimeters and to increase the speed of the process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 5712726297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sally Sakelaris

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797